

REMARKS

This Amendment is submitted in reply to the final Office Action mailed on December 13, 2007. No fee is due in connection with this Amendment. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-727 on the account statement.

Claims 1-11 are pending in this application. In the Office Action, Claims 8-9 are rejected under 35 U.S.C. §101; Claims 1-11 are rejected under 35 U.S.C. §112, second paragraph; and Claims 1-11 are rejected under 35 U.S.C. §102. In response Claims 1, 7-9 and 11 have been amended and Claim 5 has been canceled. These amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 8-9 are rejected under 35 U.S.C. §101 as allegedly being directed to improper process claims. In response, Applicants have amended Claims 8-9 to recite process steps. The amendments are supported in the specification, for example, at page 4, lines 3-25. Based on at least these noted reasons, Applicants believe that Claims 8-9 fully comply with 35 U.S.C. §101. Accordingly, Applicants respectfully request that the rejection of Claims 8-9 under 35 U.S.C. §101 be withdrawn.

In the Office Action, Claims 1-11 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In response, Applicants have amended Claims 1, 7-9 and 11 for clarification purposes to address the informalities cited by the Patent Office.

The Patent Office further alleges that Claim 2 is unclear because the elements of Claim 2 can be interpreted several different ways. Applicants respectfully disagree. For example, Claim 2 recites, in part, that the wave induction system moves from 8 to 20% of the surface area of the lower part of the culture chamber. In view of the specification, the skilled artisan would understand that the wave induction system actively moves a portion of the surface area (8 to 20%) of the lower part of the culture chamber. In other words, the remaining 80 to 92% of the surface area would not be moved at all when the wave induction system is active. Based on at least these noted reasons, Applicants believe that Claims 1-11 fully comply with 35 U.S.C. §112,

second paragraph. Accordingly, Applicants respectfully request that the rejections of Claims 1-11 under 35 U.S.C. §112 be withdrawn.

In the Office Action, Claims 1-11 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,190,913 to Singh ("*Singh*"). Claims 1-11 are rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent Publication No. 2005/0063250 to Hubbard ("*Hubbard*"). Applicants respectfully disagree with and traverse these rejections for at least the reasons set forth below.

Applicants have amended independent Claims 1 and 8-9 to recite, in part, that the wave induction mechanism lifts up between 5 and 50% of the length of the culture chamber and is compatible with large scale up. The amendment is support in the specification, for example, at the abstract, page 5 lines 23-25 and page 8, lines 29-33. In an embodiment, the mixing and aeration of the cell culture apparatus can be achieved by inducing intermittently waves from one extremity of cell culture apparatus to the other using a wave induction mechanism. By using the claimed invention, it is possible to manufacture a cell culture apparatus from flexible plastic material and use the apparatus as a disposable system. Moreover, the mixing/aeration mechanism in accordance with the present claims minimizes cell damages usually due to shear stress and small bubbles. Because the wave induction mechanism is simple, the claimed invention allows for easy and efficient scale-up from small scale to a larger one. Such a large-scale, efficient and disposable culture apparatus can largely reduce production costs of biological material such as biomass cells, embryogenic plant cells, metabolites, secondary plant metabolites and/or recombinant molecules. In contrast, Applicants respectfully submit that the cited references fail to disclose or suggest every element of the present claims.

Singh fails to disclose or suggest a wave induction mechanism that lifts up between 5 and 50% of the length of the culture chamber and is compatible with large scale up as required, in part, by Claims 1 and 8-9. In contrast, *Singh* is directed to a rocking mechanism that moves a bag back and forth thereby inducing a wave-like motion to the liquid contained therein. The rocking is obtained using a central axle (See *Singh*, Figures 1-3) and requires a powerful motor to induce the move (especially for large volumes) along with a specific table or apparatus to place the bag. See *Singh*, column 4, lines 7-33. As a result, this limits the size of the bag that can be used in *Singh*. It is unrealistic to imagine a large volume flexible container

balancing from one side to the other around the central axe because the entire culture chamber would rock periodically from one side to the other and generate very high pressure on each side, which is incompatible with a large scale up.

Hubbard fails to disclose or suggest a wave induction mechanism that lifts up between 5 and 50% of the length of the culture chamber and is compatible with large scale up as required, in part, by Claims 1 and 8-9. *Hubbard* is directed to a pressure bag this is capable of being selectively pressurized and deflated in conjunction with a disposable bio bag such as a fermenter, mixing bag or storage bag. The pressure bag may surround a selected outer portion of the bag or may be contained within an inner portion of such a bag. The pressure bag can be selectively pressurized and deflated using a pressurizing fluid supply. Accordingly, this type of the system is incompatible with a large scale-up system due to the increasing expenses associated with the increase of gas pressure and power needed to inflate the pressure bags in the larger systems.

In contrast to the cited references, the claimed cell culture apparatus provides an efficient and low cost cell culture apparatus that is compatible with large scale up. For example, the claimed cell culture apparatus does not require lifting up all the volume of the liquid in the bag as in *Singh*, but only a small part of it. Nevertheless, the wave induction mechanism is still able to generate sufficient waves for agitation/aeration of the cell culture. The claimed cell culture apparatus can require only a small motorized arm even in case of large volumes (see specification, page 6, line 27), which is not possible in *Singh*. It is easily possible to build such disposable plastic bioreactors with large volumes beyond 1000L by simply lengthening the width and length of the container and regulating the frequency of the wave generation without any change to the basic mechanism, which is not possible in either of the cited references. Finally, the large cell culture containers can be placed on any floor surface without the need for any specific table, container, etc., which is not possible with the cited references. For at least the reasons discussed above, Applicants respectfully submit that Claims 1 and 8-9 and Claims 2-7 and 10-11 that depend from Claims 1 and 8-9 are novel, nonobvious and distinguishable from the cited references.

Accordingly, Applicants respectfully request that the rejections of Claims 1-11 under 35 U.S.C. §102 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY

Robert M. Barrett
Reg. No. 30,142
Customer No. 29157
Phone No. 312-807-4204

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